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Network Meta-Analysis of Rescue Treatments for Steroid-Refractory Acute Severe Ulcerative Colitis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202430113

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 March 2024 and was last updated on 26 March 2024.

INTRODUCTION

Review question / Objective (1) P: Adult patients with steroid-refractory acute severe ulcerative colitis; (2) I: Treatment with biologics, cyclosporine, and tacrolimus. (3) C: control group without intervention; and (4) O: short-term colectomy incidence.

Condition being studied Ulcerative colitis (UC) is a chronic inflammatory bowel disease, with 20 to 25% of patients experiencing at least one acute exacerbation in their lifetime. Approximately 30% of cases of acute severe UC may require colectomy, and when first-line steroid treatment fails, biologics, cyclosporine, and tacrolimus are currently considered as second-line rescue medications. Therefore, this systematic review and meta-analysis primarily aims to investigate the short-term colectomy outcomes in steroid-refractory acute severe UC patients treated with different medications.

METHODS

Participant or population Adult patients with steroid-refractory acute severe ulcerative colitis.

Intervention Treatment with biologics, cyclosporine, and tacrolimus.

Comparator Control group without intervention.

Study designs to be included Randomized Controlled Trial, case control studies, cohort studies.

Eligibility criteria Exclusion criteria for this review and network meta-analysis included:(1)No control groups in studies; (2)Not all steroid-refractory patients included in the studies; (3)Intervention included sequential rescue therapies; (4)combination of different dosages of regimens in one group.

Information sources PubMed, Cochrane Reviews, Cochrane CENTRAL, Web of Science, and ClinicalTrials.gov databases.

Main outcome(s) Primary outcome: short-term colectomy rate. Secondary outcome: Overall mortality rate.

Quality assessment / Risk of bias analysis We utilized the Cochrane risk of bias tool for randomized trials, and the Newcastle-Ottawa Scale for nonrandomised studies.

Strategy of data synthesis Because the study encompassed different treatment regimens, a random-effects model was applied in the network meta-analysis. The analysis was conducted using MetaInsight (version 4.0.2, Complex Reviews Support Unit, National Institute for Health Research, London, UK), operating within a frequentist framework. MetaInsight is an online platform designed for network meta-analysis, which utilizes the netmeta package in R software to carry out frequentist statistical analyses. Forest and network plots were created to illustrate all pairwise comparisons from individual studies. Following this, forest plots were generated to summarize the odds ratios for short-term colectomy incidence and the risk differences in overall mortality rate for each regimen compared to the control group. The effect sizes were presented as point estimates with a 95% confidence interval (95% CI). The regimens were then ranked, and tables were provided to show numerical values for both direct and indirect comparisons. Inconsistency tests were performed to identify any discrepancies in the data. Statistical significance was determined by a two-tailed p-value of less than 0.05.

Subgroup analysis May proceed subgroup analysis according to the studies type, RCT, and non-randomized studies.

Sensitivity analysis Sensitivity analysis was performed to enhance the reliability of the study's findings. The one-study removal method was employed to verify that the effect estimates of individual studies did not disproportionately impact the overall results. By systematically excluding one study at a time from the analysis of short-term colectomy incidence, we were able to assess whether the conclusions and rankings of the study remained stable. The direction, magnitude of the effect, statistical significance, and rankings of the results were evaluated.

Language restriction No language restriction.

Country(ies) involved Taiwan.

Keywords Acute severe ulcerative colitis; Rescue therapy; Steroid-refractory; Colectomy..

Contributions of each author

Author 1 - Chih-Wen Huang - Author 1 was responsible for drafting the manuscript, as well as the methodology, formal analysis, investigation, and data extraction.

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Author 2 - Hsu-Heng Yen - Author 2 was responsible for review and editing the manuscript, as well as the investigation, data extraction data analysis and provided statistical expertise.

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